OCT 7 - 2004

1C092331

510(k) SUMMARY

(page 1 of 3)

DATE:	September 30, 2004
CONTACT PERSON:	Linda K. Dillon Chuck Lakel Pasco Laboratories 12750 West 42nd Avenue Wheat Ridge, Co 80033 303-390-3240
TRADE NAME OF DEVICE:	Pasco MIC and MIC/ID Panels
COMMON NAME:	Antimicrobial Susceptibility Test
CLASSIFICATION NAME:	Class II Antimicrobial Susceptibility Test Microbiology Panel #83

SUBSTANTIAL EQUIVALENCE:

In review of previous 510(k) notifications for the Pasco MIC and MIC/ID panels: K041776, August 3, 2004 RE: Telithromycin (Streptococcus); K041214, June 7, 2004 RE: Daptomycin (Streptococcus); K032518, September 15, 2003 RE: Gemifloxacin (Strep); K032259, August 19, 2003 RE: Gatifloxacin (Strep); K033119, November 18, 2003 RE: Daptomycin; K031727, July 30, 2003 RE: Gemifloxacin; K031205, June 13, 2003 RE: Linezolid; K031103, June 12, 2003 RE: Ertapenem; K030933, May 1, 2003 RE: Moxifloxacin; K030620, April 14, 2003 RE: Gatifloxacin; K011116, April 24, 2001 RE: ESBL Confirmatory Test; K010508, April 23, 2001 RE: ESBL Screen Test; K020331, March 20, 2002 RE: Ertapenem; K001953, August 10, 2000 RE: Amoxicillin; K001887, August 9, 2000 RE: Ampicillin; K001721, August 4, 2000 RE: Clarithromycin; K001612, July 18, 2000 RE: Linezolid; K001516, July 12, 2000 RE: Moxifloxacin; K992853, November 4, 1999 RE: Cefdinir; K992726, November 3, 1999 RE: Synercid (non-fastidious); K992717, November 2, 1999 RE: Synercid; K992646, October 19, 1999 RE: Penicillin; K992647, October 19, 1999 RE: Erythromycin; K992593, October 14, 1999 RE: Chloramphenicol; K992562, October 13, 1999 RE: Ceftriaxone; K992568, October 14, 1999 RE: Cefotaxime; K992507, October 18, 1999 RE: Trovafloxacin; K992546, October 12, 1999 RE: Meropenem; K992420, September 27, 1999 RE: Sparfloxacin; K992296, September 21, 1999 RE: Vancomycin; K992297, September 3, 1999 RE: Levofloxacin; K992143, September 16, 1999 RE: Clindamycin; K992108, September 3, 1999 RE: Cefepime; K992076, August 30, 1999 RE: Cefuroxime; K992059, August 30, 1999 RE: Imipenem; K992077, September 3, 1999 RE: Ofloxacin; K991925, August 20, 1999 RE: Amoxicillin/Clavulanic Acid; and K946126, January 17, 1995 RE: Detection of resistant pneumococci), the FDA has determined the Pasco panels to be substantially equivalent to devices marketed in

interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DESCRIPTION OF THE DEVICE:
Pasco Panels are used for quantitatively measuring the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms. Varying concentrations of antimicrobial agents (usually in two-fold dilutions) are dispensed into the Pasco microdilution panels and the panels are then frozen. Panels are thawed prior to use, inoculated with the test organisms, incubated the traditional 16-24 hours and panels are then observed for visible growth or color changes as described in the package insert.

The lowest concentration of each antimicrobial agent with no apparent visible growth of the test organism is recorded as the minimum inhibitory concentration (MIC). Changes in pH and production of specific metabolites from growth in biochemical substrates are interpreted as described in the package insert for conventional tubed media.

INTENDED USE FOR THE PASCO MIC AND MIC/ID PANELS:
PASCO MIC AND MIC/ID PANELS are used for quantitatively measuring the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms.

SUMMARY/CONCLUSION OF SUBSTANTIAL EQUIVALENCE TESTING:
Challenge strains, fresh clinical isolates, stock clinical isolates and QC strains were tested concurrently using both Pasco methodology and reference methodology in panels that contained Telithromycin at concentrations ranging from 0.015 – 4 mcg/ml. Testing was conducted at three test sites.

Test results of 207 challenge and clinical *Staphylococcus aureus* demonstrated an Essential Agreement (EA) of 100%.

QC endpoints for the NCCLS recommended QC organisms (*S. aureus* ATCC 29213 and *E. faecalis* ATCC 29212) from panels using both the reference and test methodology were acceptable.

Reproducibility testing of 10 organisms at each site on three separate days in triplicate demonstrated inter-site and intra-site reproducibility of MIC results of 100% for all three sites.

The results of the clinical testing, reproducibility testing and QC performance testing supports Substantial Equivalence as outlined in the FDA document "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 7 - 2004

Ms. Linda K. Dillon
R&D Manager
BD Diagnostic Systems
Pasco Laboratories
12750 W. 42nd Avenue
Wheat Ridge, CO 80033-2440

Re: k042331
Trade/Device Name: PASCO MIC and MIC/ID Panels for Telithromycin at 0.015-4 mcg/ml
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: August 23, 2004
Received: August 30, 2004

Dear Ms. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

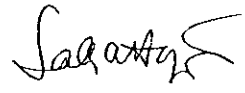
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

(6)

510(k) Number (if known): K042331

Device Name: **PASCO MIC and MIC/ID Panels** – Telithromycin 0.015 – 4 mcg/ml

Indications For Use: **Inclusion of Telithromycin**

Pasco MIC and MIC/ID panels are used for quantitatively measuring the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms.

This 510(k) notification is for the addition of the antimicrobial Telithromycin at concentrations of 0.015 - 4 mcg/ml to Pasco Panels. Telithromycin has been shown to be active *in vitro* against most strains of microorganism listed below, as described in the FDA-approved package insert for this antimicrobic.

Active *In Vitro* and in Clinical Infectious Against:

Aerobic Gram-positive microorganisms
Staphylococcus aureus (methicillin and erythromycin susceptible isolates only)

Prescription Use X **AND/OR** **Over-The-Counter Use____**
(Per 21 CRF 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042331